11146/10902

WE CLAIM:

1. In a coagulation assay for determining the propensity of patient risk for thrombotic disease wherein a phospholipid is employed as a reagent, the improvement comprising conducting said assay with an oxidized phospholipid reagent to obtain a first result and a non-oxidized phospholipid reagent to obtain a second result, and comparing said first and second result, and if said first result is prolonged in comparison to said second result, concluding that said patient is likely normal but if said first result is essentially the same as said second result, concluding that said patient likely has antibodies which block the function of oxidized phospholipids to a greater extent than unoxidized phospholipids.

2. A set of reagents for use in a coagulation assay consisting of a first reagent comprising one or more substantially non-oxidized phospholipids as determined by a ratio of the absorption bands at 233 and 215 nanometers, said first reagent maintained under oxidation-preventing gas and diluted with degassed buffer, and a second reagent comprising oxidized phospholipids prepared from a starting material of substantially non-oxidized phospholipids and subjected to controlled oxidation.

3. The set of reagents of Claim 2, wherein said phospholipids comprise phosphatidylethanolamine.

4. The set of reagents of Claim 3, wherein said phospholipids further comprise phosphatidlyserine.

5. The set of reagents of Claim 4, wherein said phospholipids further comprise phosphatidylcholine.

6. The set of reagents of Claim 5, wherein said phospholipids comprise 40% phosphatidylethanolamine, 20% phosphatidylserine and 40% phosphatidylcholine.

7. An assay to determine the presence of antibodies in a patient plasma sample, which antibodies selectively block the action of oxidized lipids, comprising:

(a) conducting a clotting assay by obtaining a first aliquot of said sample, providing activated protein C, providing an oxidized phospholipid reagent, initiating clotting and measuring the time of clotting to obtain a first clotting time;

(b) simultaneously or thereafter conducting a clotting assay by obtaining a second aliquot of said sample, providing activated protein C, providing an unoxidized phospholipid reagent, initiating clotting and measuring the time of clotting to obtain a second clotting time;

(c) comparing said first clotting time with said second clotting time and determining that the patient sample likely contains antibodies which block the function of oxidized lipids to a greater extent than unoxidized lipids if said first clotting time is essentially the same as said second clotting time.

8. The assay of Claim 7, further comprising obtaining baseline clotting values, said baseline clotting values obtained by measuring the clotting time of a third aliquot of said sample in the presence of an oxidized phospholipid reagent but without addition of activated protein C and obtaining a third clotting time baseline value, and measuring the clotting time of a fourth aliquot of said sample in the presence of a non-oxidized phospholipid reagent but without addition of activated protein C and obtaining a fourth clotting time baseline value, thereby determining if a given patient sample exhibits extended clotting time in the absence of activated protein C in comparison with a normal plasma sample, and concluding that said patient sample may have other components which may account for a prolonged clotting time when clotting time is tested in the presence of activated protein C according to steps (a) and (b).

9. The assay of Claim 7 or 8, wherein each of said phospholipid reagents comprise phosphatidylethanolamine.

10. The assay of Claim 9, wherein each of said phospholipid reagents further comprise phosphatidylserine.

11. The assay of Claim 10, wherein each of said phospholipid reagents further comprise phosphatidylcholine.

12. The assay of Claim 11, wherein each of said phospholipid reagents comprise 40% phosphatidylethanolamine, 20% phosphatidylserine and 40% phosphatidylcholine.

13. An assay to determine the propensity of a patient to have a thrombotic episode by measuring a first clotting time of a plasma sample taken from said patient in the presence of activated protein C and an oxidized phospholipid reagent , measuring a second clotting time of a plasma sample taken from said patient in the presence of activated protein C and an unoxidized phospholipid reagent, and analyzing the results, determining that said patient has a propensity for a thrombotic episode if said first clotting time is not prolonged as compared to said second clotting time.

14. The assay of Claim 13, wherein a patient immunoglobulin fraction is obtained from said plasma sample, and said immunoglobulin portion is utilized for said clotting time measurements.

15. The assay of Claim 13 or 14, further comprising diluting said plasma sample or immunoglobulin fraction thereof in an appropriate amount of normal plasma prior to measuring said first and second clotting times.

16. The assay of Claim 15, wherein said appropriate amount of normal plasma is about three parts for each one part of patient plasma sample.

17. The assay of Claim 15, wherein said appropriate amount of normal plasma is sufficient to make said immunoglobulin concentration about 0.6 mg/ml.

18. The assay of Claim 13 or 14, wherein each of said phospholipid reagents comprise phosphatidylethanolamine.

19. The assay of Claim 18, wherein each of said phospholipid reagents further comprise phosphatidylserine.

20. The assay of Claim 19 wherein each of said phospholipid reagents further comprise phosphatidylcholine.

21. The assay of Claim 20, wherein each of said phospholipid reagents comprise 40% phosphatidylethanolamine, 20% phosphatidylserine and 40% phosphatidylcholine.

22. The assay of Claim 15, wherein each of said phospholipid reagents comprise phosphatidylethanolamine.

23. The assay of Claim 22, wherein each of said phospholipid reagents further comprise phosphatidylserine.

24. The assay of Claim 23 wherein each of said phospholipid reagents further comprise phosphatidylcholine.

25. The assay of Claim 24 wherein each of said phospholipid reagents further comprise phosphatidylcholine.

26. The assay of Claim 16 or 17, wherein each of said phospholipid reagents comprise phosphatidylethanolamine.

27. The assay of Claim 26, wherein each of said phospholipid reagents further comprise phosphatidylserine.

28. The assay of Claim 27 wherein each of said phospholipid reagents further comprise phosphatidylcholine.

29. The assay of Claim 28, wherein each of said phospholipid reagents comprise 40% phosphatidylethanolamine, 20% phosphatidylserine and 40% phosphatidylcholine.